

In re National Prescription Opiate Litigation, MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum in Opposition to Defendants CVS Indiana, L.L.C. and CVS Rx Services, Inc.'s Motion for Summary Judgment

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Did CVS have compliant and effective suspicious order monitoring systems ("SOMs) in place, even after early 2014?

No. Plaintiffs set out the factual background of CVS's failure to implement a compliant SOMs going back to 2006. Although the program changed over time, it never complied with CVS's obligations under the CSA, nor was it effective in preventing the shipment of suspicious orders. Plaintiffs present evidence that the deficiencies continued in CVS's revised 2014 SOMs program, up through the time that CVS stopped distributing opioids to its pharmacies.

Issue 2: Are Plaintiffs' claims time-barred?

No. Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion for Partial Summary Judgment on Statute of Limitations Grounds, which is incorporated by reference, makes clear Plaintiffs' claims are not time barred. Because Plaintiffs do contest the adequacy of CVS's 2014 SOMs program, their tortious conduct unquestionably continued into the limitations period.

Issue 3: Have Plaintiffs produced evidence of causation?

Yes. By distributing hydrocodone combination products ("HCPs") into Plaintiffs' jurisdictions without an appropriate suspicious order monitoring program over a prolonged period of time, CVS caused or contributed to Plaintiffs' injuries. Plaintiffs incorporate by reference their arguments in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion for Summary Judgment on Proof of Causation.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

MDL 2804

OPIATE LITIGATION

Case No. 17-md-2804

This document relates to:

Hon. Dan Aaron Polster

Track One Cases

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
DEFENDANTS CVS INDIANA, L.L.C. AND CVS RX SERVICES, INC.'S
MOTION FOR SUMMARY JUDGMENT**

July 31, 2019

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INTRODUCTION

The Court should deny CVS's supplemental motion for summary judgment, Dkt. Nos. 1866 and 1889.¹ Relying on the Pharmacy Defendants' arguments in their joint brief, CVS argues that Plaintiffs' claims are barred by the statute of limitations and lack of causation. Plaintiffs rely on – and incorporate by reference here – Plaintiffs' other briefs responding to Defendants' general statute of limitations and causation arguments. Thus, this brief focuses on the relevant facts exposing the deficiencies in CVS's Suspicious Order Monitoring ("SOM") "systems," which rendered them completely ineffectual.

LEGAL STANDARD

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party." *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

¹ The CVS Defendants are CVS Indiana, L.L.C. and CVS RX Services, Inc.'s ("CVS").

FACTUAL BACKGROUND

CVS distributed hydrocodone combination products (“HCPs”) to Summit and Cuyahoga Counties until October 2014, when those products were re-classified as Schedule II in October 2014.² As detailed below, through this time period, CVS failed to comply with its obligations under the CSA.

CVS did not maintain and implement an effective suspicious order monitoring (“SOM”) program throughout the entire period that it distributed controlled substances. CVS also interfered with other distributors’ efforts to monitor CVS sales of opioids. From 2006 until August 2010, CVS did not even have written DEA Standard Operating Procedures (“SOPs”) to identify suspicious orders. In November 2007, for example, CVS was still in the process of writing the suspicious order monitoring section of its standard operating procedures.³ CVS’s corporate representative testified that as of December 1, 2007, he did not “believe that there was a [written] suspicious order monitoring policy put into place as of that date.”⁴ CVS, recognizing that it needed a DEA Compliance Coordinator, simply listed an employee’s name, Amy Propatier, in its DEA SOP Manual. Ms. Propatier admitted that her title was only for reference and not her real job position, and that the only thing she ever did related to suspicious order monitoring was to update the CVS DEA SOP manual.⁵ Thus, by its own admission, CVS lacked a written SOM policy before 2010 (40 years after the Controlled Substances Act (“CSA”) was enacted and four years after Joe Rannazzisi reminded distributors, including CVS, of its obligations under the CSA).

Instead of complying with its obligations under the CSA, from 2006 until mid-2009, the only system that CVS had to identify orders that might be potentially suspicious were known as “Pickers and Packers” and PDMR (“Viper”) Reports. Pickers and Packers worked in the controlled substance

² Report of Craig J. McCann, Ph.D., CFA, Dkt. # 2000-14 at tbls. 13, 14, 24-43.

³ Mark Vernazza Dep. (Nov. 20, 2018), Dkt. # 1971-15 at 214:22-215:10.

⁴ *Id.* at 221:5-13.

⁵ Amy Propatier Dep. (Nov. 29, 2018), Dkt. # 1969-16 at 79:15-81:2.

cage within the distribution center and they would pick and pack controlled substance orders. CVS's corporate representative testified that during this period CVS did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations; that CVS did not have a program to train its Pickers and Packers how to identify unusual orders of size, frequency, or pattern; and that he was unaware of any formal job requirements to be employed as a Picker and Packer.⁶ Instead, the Pickers and Packers would identify orders based on a "gut feeling" that an order was simply "too big."⁷ One of the Pickers and Packers, Ellen Wilson, testified that, regardless of the store or the frequency of its order, she was guided solely by a rule of thumb that she should not send out more than 12 of the small bottles, six of the larger bottles, and two or three of the largest bottles of opioids.⁸ This was the only test Wilson used, and she used it for her entire career.⁹

On its face, CVS's subjective, haphazard method was insufficient to identify orders of unusual size, and also failed completely to satisfy the two other SOM regulatory requirements to identify orders of unusual frequency or orders deviating from the normal pattern. *See* 21 C.F.R. § 1301.47. CVS's "system" predictably flagged few orders: for the Indianapolis distribution center, which supplied CVS stores in Cuyahoga and Summit counties, during the period 2006 through 2014, only one or two orders per year were flagged as requiring further approval.¹⁰ "Pickers and Packers" did not constitute a compliant SOM system.

CVS's reliance on Viper Reports is similarly unavailing. Viper Reports were not an effective SOM process – or even a SOM process at all. CVS witnesses testified that these reports were *not* designed to determine suspicious orders.¹¹ Rather, the Viper Report was an aggregate report that

⁶ Vernazza Dep., Dkt. # 1971-15 at 197:1-9; 198:3-199:2.

⁷ Ellen Wilson Dep. (Jan. 24, 2019), Dkt. # 1972-9 at 61:11-62:9.

⁸ *Id.* at 63:19-64:6.

⁹ *Id.* at 64:4-6.

¹⁰ Sherri Hinkle Dep. (Jan. 25, 2019), Dkt. # 1963-2 at 83:23-86:16.

¹¹ *See* Vernazza Dep., Dkt. # 1971-15 at 191:18-21 ("But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA.").

showed shipping versus dispensing to determine whether there was a theft of product.¹² CVS's corporate representative confirmed that that Viper Reports were not reviewed before orders for controlled substances were shipped to CVS's pharmacies.¹³ Hence, Viper Reports were not a compliant SOM system. By April 2009, CVS still did not have a suspicious ordering monitoring section in its SOPs.¹⁴ It only disseminated written guidelines, purportedly in development for three years, in the midst of a DEA inspection. John Mortelliti, from CVS's Logistics Loss Prevention, sent an email to colleagues on September 1, 2010, to provide "speaking points" to use if DEA agents visited their facilities and "question suspicious monitoring." Mortelliti urged them to "be sure your team understands it before presenting so it doesn't look like a prop instead of a tool."¹⁵

Around this time, however, CVS began using a computer algorithm that flagged potentially suspicious orders. This system created Item Review Reports ("IRR"). CVS used the IRR system until a new system was introduced in March 2014. During the period they were in use, IRRs were "the report that would flag orders for additional review."¹⁶ Although IRRs were the primary SOM "process," CVS neglected to provide written instructions for how to perform that critical review from its initial use in mid-2009 until February 29, 2012, when the first Work Instructions for Loss Prevention Analyst were instituted.

Rather than devote resources to the IRR process, however, from early/mid-2009 through early 2011, one (and only one) employee, John Mortelliti, "was taking the first pass through the IRR himself."¹⁷ According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review

¹² Terrence Dugger Dep. (Jan. 23, 2019), Dkt. # 1961-19 at 104:12-22.

¹³ Vernazza Dep., Dkt. # 1971-15 at 191:22-192:12.

¹⁴ *Id.* at 235:14-23.

¹⁵ Email from J. Mortelliti to P. Hinkle et al. (Sept. 1, 2010) (CVS-MDLT1-0000075299-75312, PSJ11-CVS Opp Exh 1).

¹⁶ Vernazza Dep., Dkt. # 1971-15 at 357:10-15.

¹⁷ Vernazza Dep., Dkt. # 1971-15 at 365:6-13; *see also id.* at 368:9-14.

and due diligence and conduct that review and due diligence as he deemed appropriate.”¹⁸ During 2009 and 2010, Mr. Mortelliti did not “identif[y] any orders that were deemed suspicious and reported to the DEA.”¹⁹

In 2012, CVS conducted time studies of the analyst who in 2012 was responsible for reviewing IRRs for half the country. The study demonstrates how little time CVS spent in reviewing potentially suspicious orders, with as little as 15 minutes spent to review some IRRs, with very few orders investigated.²⁰

CVS’s corporate representative testified that “for the most part,” if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order.²¹ Even then, one CVS employee testified that he investigated 5% or less of the IRR flagged orders.²² According to CVS policy, whenever an order received due diligence beyond a simple review of the IRR, that review was to be attached to the IRR and documented on the IRR Recap.²³ Review of the IRR Recap Reports shows that during the height of the opioid crisis, CVS undertook just *three* investigations of HCP orders in Summit and Cuyahoga counties.²⁴ The number of CVS orders of controlled substances in Cuyahoga and Summit counties identified as potentially suspicious and investigated by CVS stands in stark contrast to the number of orders identified by Plaintiff’s expert Craig McCann who, after analyzing ARCOS data for CVS orders, determined, based on a number of metrics, that CVS should

¹⁸ *Id.* at 371:15-23.

¹⁹ *Id.* at 374:7-11.

²⁰ The evidence has shown that IRRs ranged from dozens of pages to hundreds (approaching thousands) of pages. Despite the size of the IRRs, some of these were only reviewed for 15 minutes: For example, a 9/6/12 IRR was at least 33 pages (*see* CVS-MDLT1-000123520-123533, CVS-MDLT1-000123512-123514 & CVS-MDLT1-000123508-123511, together PSJ11-CVS Opp Exh 2); and a 7/3/12 IRR was at least 26 pages (*see* CVS-MDLT1-000123708-123733, PSJ11-CVS Opp Exh 3).

²¹ Vernazza Dep., Dkt. # 1971-15 at 392:20-393:7.

²² Gary Millikin Dep. (Jan. 11, 2019), Dkt. # 1968-1 at 213:12-214:12.

²³ Burtner Dep., Dkt. # 1959-13 at 404:24-405:10; 474:23-475:8; Pamela Hinkle Dep. (Jan. 24, 2019), 130:8-131:1, PSJ11-CVS Opp Exh 4.

²⁴ *See, e.g.*, Burtner Dep., Dkt. # 1959-13 at 488:6-490:4 & CVS-MDLT1-000009740-9798, PSJ11-CVS Opp Exh 5 (one order flagged between January 2011 and June 2012); Burtner Dep., Dkt. # 1959-13 at 485:20-487:1 (one order investigated between February 2013 and December 2013); Shauna Helfrich Dep. (Jan. 10, 2019), Dkt. # 1962-28 at 142:17-143:22 (one store with two orders on the same day investigated between January 2014 and February 2014).

have conducted a complete examination and investigated tens of thousands of potentially suspicious orders during the relevant time period.²⁵ The IRR “process” was neither an effective nor compliant SOM system.

CVS’s internal documents demonstrate additional flaws in the IRRs. On October 8, 2010, an employee responsible for suspicious order monitoring reported that “[t]he current IRR does not provide the proper information to meet the DEA’s needs.” Orders are monitored by drug, not active ingredient, and any change in a drug’s description causes a loss of all historical data. CVS accurately determined that the “IRR loses all order history when the info on the item changes causing CVS to be noncompliant with DEA expectations.”²⁶ It took CVS over 8 months to fix this issue, in spite of numerous emails documenting it.²⁷

In addition, during early/mid-2009 to March 2014, CVS’s IRRs did not consider orders delivered to CVS pharmacies by outside vendors.²⁸ CVS had full access to every order its pharmacies placed to outside vendors but did not incorporate this information in its SOM “system.” In fact, if CVS detected an order to an outside vendor that CVS identified “as an order deviating from the normal size, frequency, and/or buying pattern and deemed to not be for legitimate purposes or are at risk of being diverted [those orders] are *not* required to be reported to the DEA.”²⁹

CVS’s internal assessment of the need to track orders of controlled substances from outside vendors concluded that it is required by “DEA’s ‘Know Your Customer’ requirements.”³⁰ CVS

²⁵ McCann Report, Dkt. # 2000-14 at 56-81 (identifying various thresholds to measure potentially suspicious orders of hydrocodone for CVS stores such as: ‘Trailing Six-Month Maximum Threshold (█████ Cuyahoga) █████ Summit) at pp. 58-59; Twice Trailing Twelve-Month Average Pharmacy Dosage Units (█████ Cuyahoga) █████ Summit County), pp. 62-63; Three Times Trailing Twelve-Month Average Pharmacy Dosage Units (█████ Cuyahoga) (█████ Summit) pp. 66-68; Maximum 8,000 Dosage Units Monthly Threshold (█████ Cuyahoga) █████ Summit), pp. 70-72; Maximum Daily Dosage Units Threshold (█████ Cuyahoga) █████ Summit), pp. 74-76).

²⁶ CVS-MDLT1-000034175-34177, at 34175, PSJ11-CVS Opp Exh 6.

²⁷ CVS-MDLT1-29864-29866, PSJ11-CVS Opp 7; Henry John Mortelliti, III Dep. (Jan. 23, 2019), 129:11-131:11, 177:12-20, PSJ11-CVS Opp Exh 8; Ex. 16 to Mortelliti Dep. (CVS-MDLT1-000034175-34177, PSJ11-CVS Opp Exh 6).

²⁸ Burtner Dep., Dkt. # 1959-13 at 284:21-285:20.

²⁹ CVS-MDLT1-000078060-000078069 at 78068, PSJ11-CVS Opp Exh 9 (emphasis added).

³⁰ CVS-MDLT1-000103327-000103328 at 103328, PSJ11-CVS Opp Exh 10.

acknowledged a “[s]tore may order a little from both the OV [outside vendor] and DC [distribution center] to stay under radar” and, especially tellingly, “we may ship a potentially reportable suspicious order from our DC” if these orders are not tracked in real time.³¹ CVS’s internal investigation revealed that one of its pharmacies lost 68,000 hydrocodone pills and was still placing phone orders to outside vendors. *Id.*

CVS consistently under-staffed its program to review suspicious orders. At times CVS had a single employee reviewing all controlled substance orders for the entire country. On July 9, 2013, a CVS SOM analyst wrote: “I did want to highlight to the group that you note that I do NOT have any backup. Even our hourly assistant has limited access. If something happens to me via act of nature or illness, the current daily SOM process would come to a complete halt.”³² In addition to being understaffed, CVS failed to use current data to conduct its due diligence reviews. A July 11, 2013 email from a CVS SOM Analyst acknowledged that the data in Store Metric Reports, used to conduct due diligence reviews of suspicious orders, was *a year old* by the time it reached the analyst. Thus, “[a]ny analysis that I make from the data is, for the most part, irrelevant and pointless.” The email concludes: “In any event, the big issue is of false negatives and the risks associated with something slipping by.”³³

CVS implemented a new suspicious order monitoring system in the Indianapolis distribution system in March of 2014. The new system also failed to prevent diversion throughout the period that CVS distributed hydro-combination products. When the system was rolled out in early 2014, a CVS employee sent an e-mail describing the system, [REDACTED]³⁴ The deployment was further delayed due to system data feed issues that created inaccuracies in the SOM historical

³¹ *Id.*

³² CVS-MDLT1-000076114-76117, at 76115, PSJ11-CVS Opp Exh 11.

³³ CVS-MDLT1-000078116-78119, at 78117, PSJ11-CVS Opp Exh 12.

³⁴ CVS-MDLT1-000017246, PSJ11-CVS Opp Exh 13.

data.³⁵ A risk analysis of the new system was conducted in June of 2014. The risk level was determined to be high for the suspicious order monitoring system in the following categories: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; lack of clarity in how the new SOM system is identifying suspicious orders.³⁶ Even under the new system, CVS' own internal documents reveal that there was a high risk of diversion of controlled substances in at least six different areas. All of these facts undermine CVS's contention that summary judgment is required as to the new suspicious order monitoring system installed in early 2014.

CVS admitted to the DEA during an investigation that began in 2013 of the Indianapolis distribution center that CVS identified and reported to the DEA only seven suspicious orders across the entire country.³⁷ Not a single suspicious order was reported to the DEA for shipments into Summit or Cuyahoga counties.³⁸ At the conclusion of the DEA audit in 2015, the DEA determined that CVS violated the Controlled Substances Act. The DEA found that CVS "failed to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5). . . ."³⁹ The

³⁵ CVS-MDLT1-000030176, PSJ11-CVS Opp Exh 14.

³⁶ CVS-MDLT1-000103342-103343, PSJ11-CVS Opp Exh 15.

³⁷ Mark Nicastro Dep. (Dec. 6, 2018), at 206:3-209:9, PSJ11-CVS Opp Exh 16; CVS-MDLT1-000000409-000420 at 417, PSJ11-CVS Opp Exh 17; CVSMDLT1-000000421-422, PSJ11-CVS Opp Exh 18.

³⁸ Nicastro Dep. 211:14-20, PSJ11-CVS Opp Exh 16. *See also* CVS's written Responses to Topic 14 at p. 3 of Plaintiffs' Amended Second Notice of Deposition Pursuant to Rule 30(b)(6), PSJ11-CVS Opp Exh 19 ("CVS has not located information indicating that it identified a suspicious order for an HCP arising out of the Track One Jurisdictions during the relevant time period.").

³⁹ CVS-MDLT1-000008014-8015, PSJ11-CVS Opp Exh 20. The DEA's conclusion was supported by its identification of CVS pharmacies in rural Indiana. One of those stores ordered REDACTED tablets, of which REDACTED tablets were sold by the Indiana distribution center from January 1, 2012, through October of 2013, for a town of 45,000 people. While this was discovered in Indiana, the same system was in place across the entire country, including in Summit and Cuyahoga counties. *See also* Nicastro Dep., 287:21-289:12, PSJ11-CVS Opp Exh 16.

DEA withheld issuing its final decision regarding its 2013 audit of CVS until it was sure that CVS discontinued all distribution of hydrocodone combination products in 2014.⁴⁰

The off-the-charts ordering patterns of CVS stores should have alerted CVS to the existence of potential diversion or suspicious orders by these stores. In 2010, for example, a Florida CVS pharmacy's 10-month history showed quantities more than 30 times the amount of oxycodone a typical pharmacy orders in one year. One Florida CVS pharmacy set a daily limit of oxycodone 30mg prescriptions (based on the amount in stock) that the pharmacy would fill each day, to ensure that the "real pain patients" could get their prescriptions filled. Customers, aware that prescriptions were first come, first serve, would line up outside the store as early as 7:45 AM. A CVS employee acting as "bouncer" included escorting off the premises customers who were "hooked" on opioids in his job duties. All of these facts were documented in an enforcement action filed against CVS by the DEA.⁴¹ CVS has been investigated by the DEA for violations of the Controlled Substances Act on numerous occasions. Between 2013 and 2018 CVS paid over \$55 million dollars in settlements to the DEA for alleged violations of the Controlled Substances Act.⁴²

CVS also conspired with Cardinal and McKesson to allow CVS to purchase controlled substances from these distributors without being constrained by any effective suspicious order monitoring. This fact is highlighted in the February 2, 2012 DEA Order to Show Cause and Immediate Suspension of Registration issued against CVS. The Order outlined that from January 1,

⁴⁰ CVSMDLT1-000022230-31, PSJ11-CVS Opp Exh 21. *See also* Nicastro Dep., 285:24-288:152, PSJ11-CVS Opp Exh 16.

⁴¹ Decl. of Joseph Rannazzisi, ¶¶ 38-41, *Holiday CVS, L.L.C. d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191 (D.D.C. Feb. 24, 2012), Doc. No. 19-6, PSJ11-CVS Opp Exh 22.

⁴² *See* PSJ11-CVS Opp Exh 23 (AL: Moffatt Tr. at 204:24-207:11 and CVS-MDLT1-00060812-60821; CA: Moffatt Tr. at 222:22-231:8 and CVS-MDLT1-00060856-60871; CT: Moffatt Tr. at 250:21-254:2 and CVS-MDLT1-000060830-60838; FL: Moffatt Tr. at 175:3-177:15 and CVS-MDLT1-00060798-60804; MD: Moffatt Tr. at 200:6-204:22 and CVS-MDLT1-000060805-60811; MA: Moffatt Tr. at 259:15-260:3 and CVS-MDLT1-000060872-60906; NY: Moffatt Tr. at 241:22-248:8 and CVS-MDLT1-000060839-60846; OK: Moffatt Tr. at 216:15-218:3 and CVS-MDLT1-00060822-60829; RI: Moffatt Tr. at 218:5-222:21 and CVS-MDLT1-00060847-60855; TX: Moffatt Tr. at 237:17-241:21 and CVS-MDLT1-000060915-60921; TX II: Moffatt Tr. at 260:4-261:24 and CVS-MDLT1-000060907-60914).

2008, through December 31, 2011, CVS Store 219 purchased over REDACTED dosage units of oxycodone from its distributors; and CVS Store 5195 purchased over REDACTED dosage units of oxycodone from its distributors.⁴³ This conduct also resulted in the DEA revoking the registrations of these two CVS stores and CVS acknowledging that certain “retail stores did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations.”⁴⁴

CVS failed to implement any monitoring and reporting system related to controlled substances it purchased from Cardinal or McKesson. Not only did it fail to monitor, but on the off-chance it would discover a suspicious order shipped from Cardinal or McKesson, CVS directed employees not to notify the DEA:

“[controlled substance] orders that are placed to an Outside Vendor that we identify as an order deviating from the normal size, frequency, and/or buying pattern and deemed to *not be* for a legitimate purposes or are at risk of being diverted *are not required to be reported to the DEA.*”⁴⁵

Additionally, CVS, Cardinal, and McKesson understood that the distributors would require access to certain CVS information to do appropriate due diligence – yet the information was never provided. In an email from Paul Farley to Michael Mone, both Cardinal employees, Farley writes, “I spoke with Brian Whalen at CVS a couple of times this morning . . . They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this.”⁴⁶ Similarly, CVS had McKesson agree to a process such that if a CVS pharmacy placed a potentially suspicious order, McKesson would not conduct any due diligence to determine whether

⁴³ Attachments C and D to Decl. Michele M. Leonhart, *Holiday CVS, L.L.C. d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191 (D.D.C. Feb. 24, 2012), Doc. Nos. 19-4 & 19-5, PSJ11-CVS Opp Exh 24.

⁴⁴ Settlement Agreement, CVS-MDLT1-000060796-60804, at 60798, PSJ11-CVS Opp Exh 25.

⁴⁵ Craig Schiavo Dep. (Jan. 17, 2019), at 257:9-258:1, PSJ11-CVS Opp Exh 26. *See also* Schiavo Ex. 16 at CVS MDLT1-000078060-78069 at 78068, PSJ11-CVS Opp Exh 9.

⁴⁶ Donald Steven Morse Dep. (Dec. 13, 2018), Dkt. # 1968-9 at 115-116) & Ex. 4 to same, PSJ11-CVS Opp 32.

the order was suspicious. Instead, McKesson would contact CVS corporate headquarters and allow CVS personnel to investigate the order.⁴⁷

The CVS and Cardinal conspiracy to violate the CSA was so brazen that the parties actually entered into a contract that contractually guaranteed CVS' right to establish and change its own threshold requirements for controlled substances ordered from Cardinal. The agreement expressly states that CVS has the discretion under the contract to set its threshold quantities for controlled substances at any level CVS deems appropriate:

CVS requires the ability to adjust (up or down) the quantity of product our stores receive. This adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. **Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.**⁴⁸

ARGUMENT

I. PLAINTIFFS' CLAIMS AGAINST CVS ARE NOT TIME-BARRED

CVS claims that "the longest possible statute of limitations applicable to plaintiffs' claims is four years," relying on Defendants' statute of limitation motion. CVS Mem. 2 n.2 (citing Dkt. No. 1703-1 at 2). CVS is incorrect. As discussed in detail in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion for Partial Summary Judgment on Statute of Limitations Grounds, and incorporated by reference herein, Plaintiffs' claims are not time barred because the statute of limitations does not apply to Plaintiffs' equitable public nuisance claim for abatement; the statute of limitations for unjust enrichment claims runs from the date the misconduct ended; the statute of limitations is tolled under the doctrine of equitable tolling; and the statute was tolled due to defendants' fraudulent concealment, among other reasons.

⁴⁷ Michael Oriente Dep. (July 19, 2018), 547:12-550:1, PSJ11-CVS Opp Exh 27.

⁴⁸ (Emphasis added.) See Ronald Link Dep. (Dec. 11, 2018), at 65:12-67:7 (attached as PSJ11-CVS Opp Exh 28) & Ex. 50 to same (CVS-MDLT1-000030817 at CVS-MDLT1--000030869, attached as PSJ11-CVS Opp Exh 29). See also January 1, 2004 contract between CVS and Cardinal (CVS-MDLT1--00030892 at CVS-MDLT1-00030947, PSJ11-CVS Opp Exh 30), and July 1, 2007 contract between CVS and Cardinal (CVS-MDLT1-000030995 at CVS-MDLT1-000031041, PSJ11-CVS Opp Exh 31), both contracts containing similar language.

II. THERE IS A GENUINE ISSUE OF MATERIAL FACT ABOUT WHETHER CVS'S CONDUCT WAS A SUBSTANTIAL FACTOR IN CAUSING THE OPIOID CRISIS IN CUYAHOGA AND SUMMIT COUNTIES

With respect to CVS's causation argument, CVS Mem. 3-5, Plaintiffs' hereby incorporate by reference their arguments in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion for Summary Judgment on Proof of Causation. Moreover, CVS explicitly acknowledges that CVS accounted for █████ of the relevant prescription opioids shipped to Summit and Cuyahoga from 2006 through 2018 based on MMEs.⁴⁹ The CVS statistic of █████ is also grossly misleading because it uses a time period through 2018. CVS stopped distributing opioids when HCPs were rescheduled in 2014.⁵⁰ Therefore, the percentage of relevant prescription opioids is actually larger because four years were lopped off CVS's distribution time frame. The actual number of HCP pills (dosage units) CVS distributed into Cuyahoga and Summit Counties was REDACTED, which is hardly de minimus.⁵¹ By dosage market share, CVS had REDACTED% of the opioid market share in Cuyahoga County and REDACTED% in Summit County from 2006-2014.⁵²

CVS also claims the fact they only distributed HCPs weakens Plaintiffs' causation argument.⁵³ But as the DEA noted, "[t]he data indicate that HCPs and oxycodone products have similar abuse potential. Based on these considerations, the DEA believes that the high abuse and dependence potential and harm associated with HCPs support rescheduling into schedule II of the CSA."⁵⁴ In a "Drug Fact Sheet," the DEA stated that "[h]ydrocodone is the most frequently prescribed opioid in

⁴⁹ CVS Mem. 4.

⁵⁰ *Id.* at 2.

⁵¹ McCann Report, Dkt. # 2000-14 at 3783, 3852.

⁵² *See id.*

⁵³ CVS Mem. 4.

⁵⁴ DEA Final Rule: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 C.F.R. 49,667 (Aug. 22, 2014), https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm#startcontent.

the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid.”⁵⁵ There is no reason for CVS to tout the fact that it just distributed HCPs.

Finally, CVS’s citation to *Queen City Terminals, Inc. v. General American Transportation Corp.*, 73 Ohio St. 3d 609, 653 N.E.2d 661 (1995), for the proposition that “[w]here a plaintiff suffers a single injury as a result of the tortious acts of multiple defendants, the burden of proof is upon the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm,” is surprising. CVS Mem. 5. The *Queen City Terminals* court held that “the ‘substantial factor’ test is used to determine liability when factors other than the negligence of the tortfeasor may have caused the plaintiff’s damages,” but went on to hold that “[t]he determination of whether an actor’s conduct was a substantial factor in producing the plaintiff’s injury is a question of fact to be determined by the trier of fact.” 73 Ohio St. 3d at 617-18, 653 N.E.2d at 669 (emphasis added). Accordingly, CVS’s own authority makes clear that summary judgment is improper.

CONCLUSION

The Court should deny CVS’s motion for summary judgment.

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Respectfully submitted,

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⁵⁵ See Pls.’ Omnibus Opp’n to Mfr. Defs.’ Joint Objects. & Pharmacy Defs.’ Objs. to Special Master’s Disc. Rulings No. 2 & 3, at 22-23, Dkt. # 812 (quoting DEA Drug Fact Sheet).

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